

Food and Drug Administration

Docket Number: 2002N-0276

Webpage: www.fda.gov/OHRMS/DOCKETS/98fr/04-8516.htm

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Comments

- 1) **Requirement For a US Agent** – this requirement does not, in our view, influence the effectiveness of the Bioterrorism Act in any way. Entities that ship food products into the USA are already registered with their own governments, their products must meet the regulatory requirements of Customs and the FDA, and they must still comply with the Prior Notice requirements for shipments of food-related products. Registered facilities are required to provide emergency contact information. Such contact is permitted to be anyone associated with the facility and can be a resident of any country. The only requirements for a US agent are: they must reside or have a place of business in the US and must be physically present in the US. The US agent is not required to have any knowledge of the facilities' products or processes. The usefulness of the US agent in terms of assisting authorities in tracking or handling of a bio-terrorism attack against the USA through a shipment from any registered facility is suspect. The requirement for a US agent adds an unnecessary regulatory layer to the process of doing business in the USA.